

PSJ10 Exh 48

## Summary

The Dallas Advisory Board meeting was significantly different from the National advisory Board meeting in Hoboken in terms of the discussion around clinical practice, reaction to the study data and to the MOXDUO® materials presented. In light of the feedback provided, it might make sense to re-think aspects of both the Marketing and Prescriber Targeting plans.

## Key Takeaways

- The issues of misuse, abuse and diversion are part of daily practice for many HCP. There was general agreement that the companies marketing opioid medications have played a role in creating the problem.
- Getting orthopedic patients out of the in-patient setting faster has little to do with surgical technique and everything to do with pain management
- We have to make this simple for prescribers
- The clinical data was perceived as being only moderately compelling.
- The majority of dosing is likely to be for 3:2 and 6:4
- Under-treatment of acute pain can potentiate development of/progression to chronic pain
- Perry Fine suggested positioning MOXDUO® as an opportunity for prescribers to upgrade their understanding of effective pain management. He articulated the concept of 'thoughtful acute pain management'
- General agreement that the possible up-scheduling of hydrocodone will change the market considerably; One board member (Fine?) went so far as to suggest that hydrocodone is the real competition to MOXDUO®
- James North stated that we need to market the product to people who are actually dealing with side effects – i.e. in many cases, this is the nurses
- William Long: The Nucynta® story is compelling, but cost structure has made it "not simple". Patients had problems getting prescriptions filled and it does not take many problems to turn prescribers off...it has to be simple.
- "This is a niche product." (James North)
- Q: What portion of the IR scripts written by Anesthesia/Pain and PM&R is written for chronic pain and/or breakthrough pain? A: "All of it." (Standiford Helm)
- Two thirds of your targets treat chronic pain. There is very no synergy between KADIAN® prescribers and potential prescribers of MOXDUO®. (Standiford Helm).
- The group was blasé about the proposed abuse-deterrent formulation. The majority of abuse is oral, and physical deterrents have little effective positive impact

## Discussion

Actavis has an opportunity to differentiate itself based on open acknowledgement of the problems and risks surrounding opioid therapy

Suggestions for



REMS

Blister-pack supply: clearly sets the expectation that a patient will not be on pain medication for an extended period

Provide clear, explicit instructions for safe disposal

Suspicious order monitoring

Partnership with Walgreen's

Acute pain only

We may need to develop a piece at launch, which succinctly explains 3:2 and multiple receptors